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User's Manual

IO-005 Electrolyte Analyzer

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1 Introduction

1.1 Usage

K+, Na+, Cl- and Ca++ are important constituents of blood. Only if these constituents are in normal range people can keep fit. IO-005-electrolyte analyzers are based on ISE (Ion selectivity electrode) for measuring ions, which is quick and accurate. Samples can be whole blood, serum, plasma and urine.

Before operation, please read the manual carefully!

1.2 Application

The application of EA series is diversified. Details are shown as Table1.

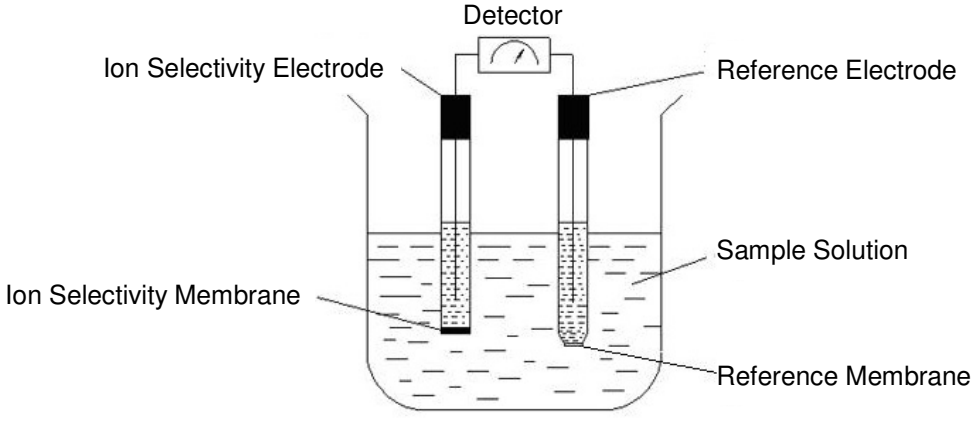
Table1 Application of EA series

Model	Application
IO-005	K+, Na+, Cl- ,Ca++ ,PH

1.3 Principle of Ion Selectivity Electrodes

1.3.1 Introduction

The principle is developed according to potentiometer between ion electrode and reference electrode. Most of salt in electrolyte solution is in ion state. The electronic exchange between electrode and solution forms an electronic flow which represents the ion concentration.



The above reaction follows the formula of Nernst's:

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$$E = E_0 + \frac{2.303RT}{nF} \log a_x f_x$$

Where，

E-- The voltage value of ion selectivity electrode in the measured solution

T-- Absolute temperature

E_0-- Standard value of voltage of selectivity electrode

F-- Faraday constant

n-- Electric charge of the ion measured

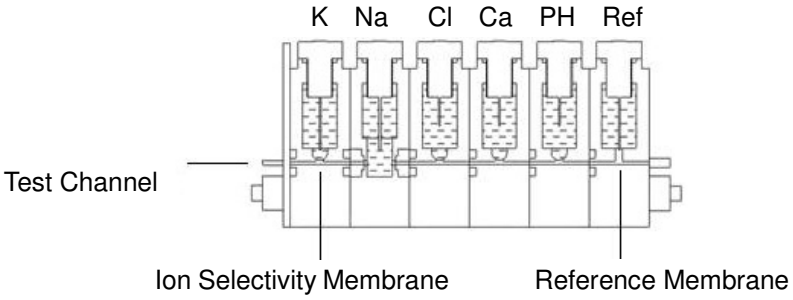
a_X-- The activity of ion measured

R-- Gas constant

f_X-- The activity modulus of the ion measured

1.3.2 The Structure of EA Ion Selectivity Electrode

EA electrolyte analyzer measures the concentration of ion by using different models of ion selectivity electrodes, including: K+, Na+, Cl-, Ca++, PH and reference electrode.



1.3.3 The Principle of Measurement

Using the method of comparison, electrolyte analyzer measures the concentration of K+, Na+, Cl- Ca++ and PH. The measurement steps are as follows:

-- Measure two known standard solutions (standard A and standard B) to get two potential values of electrode, set up calibrating curve referring to the measurement.

-- Measure the electrode potential of sample and compares with calibrating curve to get its result. The following figure shows the measurement principle.

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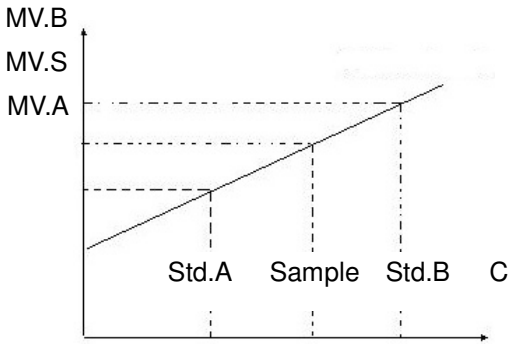

1.4 Basic Technical Specifications

The basic technical specifications of IO-005 are shown as Table2.

Table2 Basic Technical Specifications

Item	Range	Precision
K	0.5-10mmol/L	CV≤1.0%
Na	50-200mmol/L	CV≤1.0%
Cl	50-200mmol/L	CV≤1.5%
Ca	0.2-5mmol/L	CV≤2.0%
PH	6-9	CV≤1.0%

1.5 The Structure of Analyzer

1.5.1 Front View

Figure 1

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1.5.2 Back View

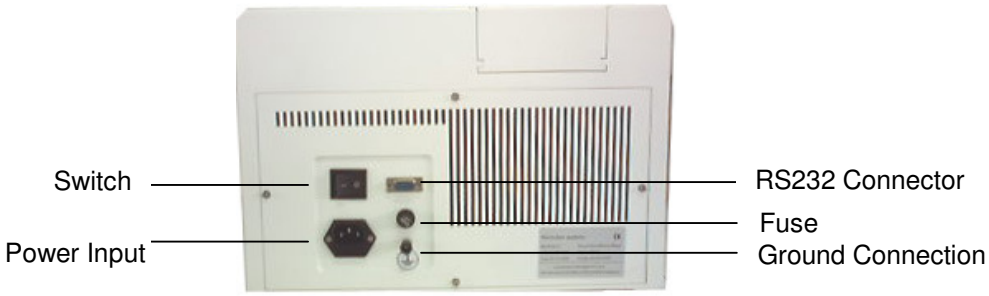

Figure 2

1.5.3 Main Components

EA components include electrode holder, pump, valve, waste container, reagent container as shown in Figure3.

Figure 3

2 Installation

2.1 Working Conditions

Power: 220V 50HZ / 110V 60HZ

Temperature: 10℃-35℃

Humidity: < 85%

Others: The analyzer has to keep away from electromagnetism field & heating source. Also it has to be very well ground connected, avoid exposure to direct sunlight, ultraviolet and radiation. Moreover, it has to be set in clean

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environment.

2.2 Reagents and Consumables

Reagents and consumables are shown as Figure 4 – 9.

Standard A

Figure 4

Standard B

Figure 5

De-protein Solution

Figure 6

Electrode Electrolyte

Figure 7

Reference Electrolyte

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Figure 8

Print Paper

Figure 9

2.3 Unpack and Installation

2.3.1 Check Contents

Once the goods is received, please check its package and contents referring to packing list. For any damage or loss, please contact forwarder or our local distributor.

2.3.2 Installation

Steps are as follows:

-- Mount the analyzer on surface of a table or a desk.

-- Open the seal of reagent Standard A and B, insert reagent tube in each container, and then position Standard A and B in reagent chamber referring to Figure 3.

-- Insert waste tube into the waste container and position the container in the chamber referring to Figure 3.

Note: The end of tube must reach the bottom of reagent container. But the waste tube should be placed on the upside of waste container.

-- Install the peristaltic pump tube on the pump wheel shown as Figure 10.

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Figure 10

-- Check if the electrodes and the holder are fixed well.

Note: The sequence of electrodes from left to right is k+, Na+, Cl^-, Ca++, PH and Reference electrode.

How to disassemble the electrode holder are shown as Figure 11–13.

a. Disconnect tube as shown in Figure11.

Figure 11

b. Take out the electrode holder as shown in Figure12.

Push the bottom of the holder upward (only a little bit) and then drag the holder out.

Figure 12

c. Check the electrodes and the holder as shown in Figure13.

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Figure 13

3 Operation

3.1 Start-up

Press key “POWER”

3.2 Setup

a. “Clindiag EA 5” (or “Clindiag EA-3”, or “Clindiag EA-2”) on display

b. Automatic ring

c. Show “System Testing”

d. Automatic print “Clindiag EA 5” (or EA-3, or EA-2)

e. Show “Flushing!”

f. Show “Calibrate A”

g. 50 to 60s later: show “Cal A____MV “

h. Aspiration of standard B: show “Calibrate B”

i. 50 to 60s later: show” Cal B____MV”

j. In the process of above steps the analyzer automatically calibrates itself. When the calibration is completed, it is ready for testing. The display shows as Figure 14.

Main Menu	
Test	QC
Setup	Service

Figure 14

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3.3 Main Menu

3.3.1 Test

Select ”Test” and then the display shows as Figure15.

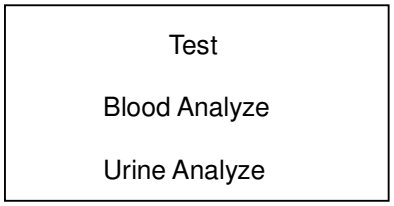

Figure 15

3.3.1.1 Blood Analyze

Press “NO” to return to the main menu, select “Blood Analyze” to enter blood test program. The display shows as Figure16.

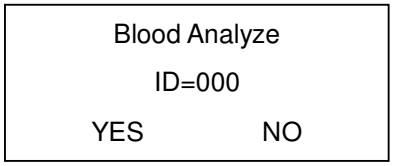

Figure 16

Press “YES”. The display shows as Figure17.

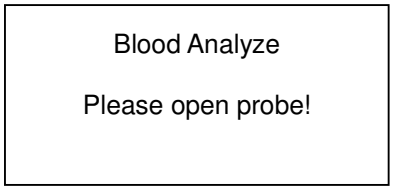

Figure 17

Open probe. The display shows as Figure18.

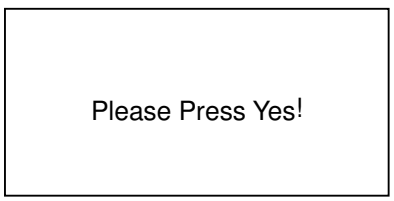

Figure 18

Place sample tube under probe and make sure the head of probe reaches the sample. Press key “yes”, the analyzer will aspirate the sample and start

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testing. The display shows as Figure19.

Figure 19

After the sample is aspirated into probe, the probe must be pushed back within 10 sec, otherwise the analyzer will give an alarm. Now the display shows as Figure20.

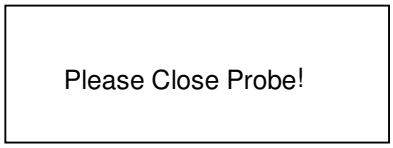

Figure 20

After closing the probe the display shows as Figure21.

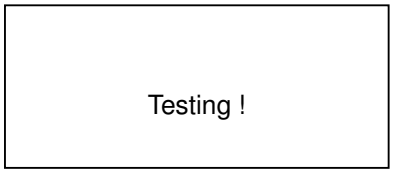

Figure 21

When test is finished, the results are displayed (for example) as Figure22.

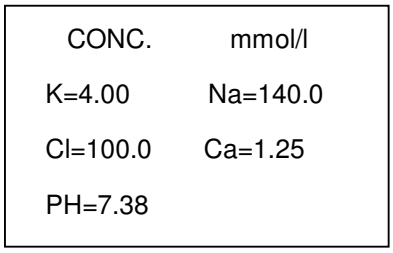

Figure 22

Then analyzer automatically washes electrode and prints report. The display shows as Figure23.

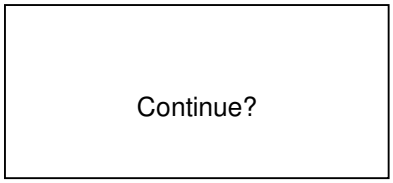

Figure 23

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Press key “Yes” to test another sample; Press “PRINT”, the printer will print out one more report.

Press “CAL” the analyzer calibrates again.

Press “NO” to return to main menu.

Urine test and QC test run by the same steps as blood test.

3.3.1.2 Urine Test

Choose Urine test to enter urine analysis steps. The display shows as Figure24.

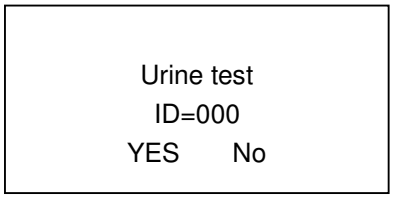

Figure 24

The process is the same as test blood

Note: Urine must be diluted before test. Dilution method: mix 100ul urine sample with 900ul ion-free water.

3.3.2 Quality Control

3.3.2.1 General Introduction

Thanks to the analyzer’s excellent QC design, we recommend user perform QC tests by installation, or every month or change reagent or in any necessary case.

Choose “Q.C.” in the main menu, the display shows as Figure25.

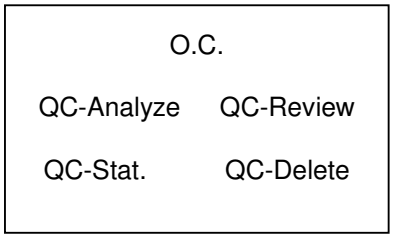

Figure 25

“QC-Analyze” is to check if the analyzer can produce correct result or not. If QC is out of range, the analyzer can not produce correct result and then the

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user has to check the instrument and the reagent. EA analyzer can perform three level controls (high, normal and low.). Choose “QC-Analyze “to enter QC analysis program, the display shows as Figure26.

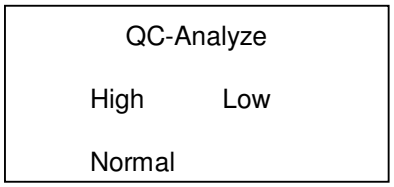

Figure 26

If user wants to analyze the high level, please choose “High”. The display shows as Figure27.

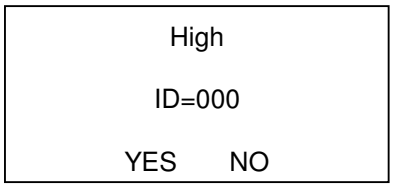

Figure 27

Press “NO” to return to previous page. Press “YES” to confirm.

.

3.3.2.2 Data Statistic

According to QC test data, the “QC STAT” function can work out: AVERAGE, SD and CV.

Select “QC-Stat.” to enter QC stat program, the display shows as Figure28.

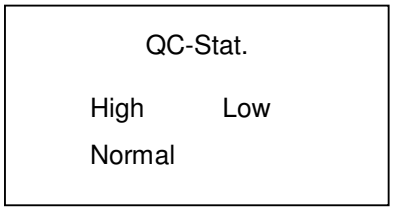

Figure 28

Choose “High”. If data exists, the display shows as Figure 29.

“11” means 11 QCs are tested and “30” means 30 QC tests can be saved at this level.

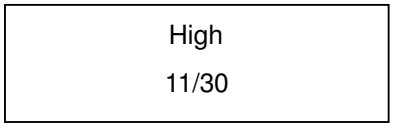

Figure 29

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Press key “YES,” the display shows as Figure30.

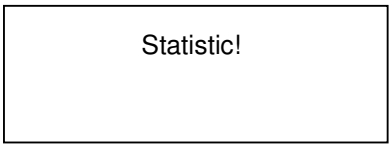

Figure 30

The display shows the statistic data by following sequence: SD, AVERAGE and CV.

First is “SD shown as Figure31.

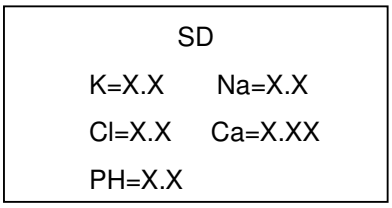

Figure 31

Press “YES”, the display shows as Figure32.

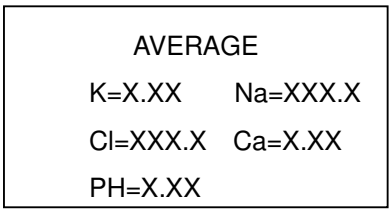

Figure 32

Press “YES” again, the display shows as Figure33

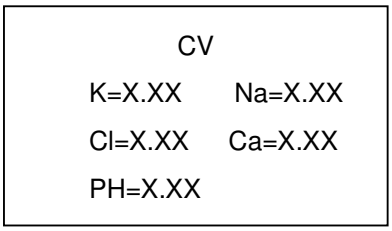

Figure 33

Press “YES” again to print out all the statistic data.

Press “NO” to go back to QC menu.

If less than 5 QC tests are stored, the analyzer can not give statistics data

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and the display shows as Figure34.

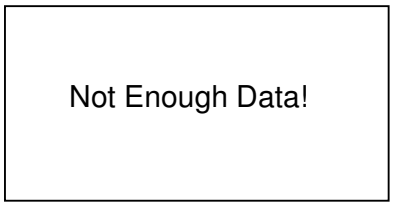

Figure 34

Choose “QC-Review” to review the data.

Choose “QC-Delete” to delete all the data.

3.3.3 System Setup

IO-005- analyzer’s system has to be set after startup. Choose “Setup” to enter setup menu. The display shows as Figure35.

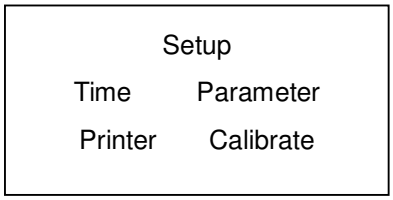

Figure 35

Set up data, time, parameter, printer or the model of calibration.

3.3.3.1 Time Setup

Choose “Time” in the Setup menu. The display shows as the Figure 36. Key “Up” and” Down” can change number and Key “Right” and “Left” perform modification. Press “YES” to save and then return to the Setup menu. Press “NO” to cancel.

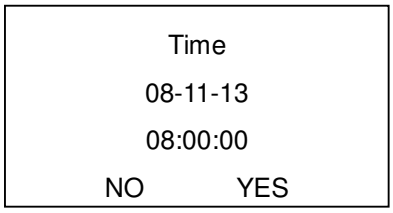

Figure 36

3.3.3.2 Printer Setup

Choose Printer in the Setup menu, then the display shows as Figure37.

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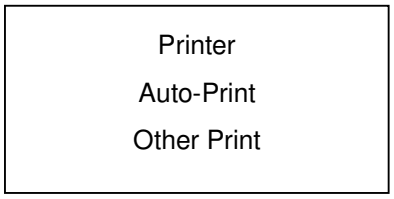

Figure 37

Then choose Auto-Print, the display shows as Figure38.

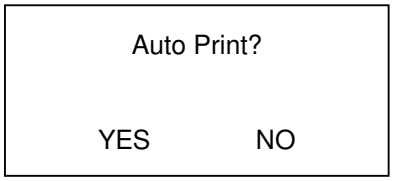

Figure 38

Choose “YES” to print every test result automatically

Set other print function as Figure 39: to activate the print function by selecting each item. “YES” to print, “NO” not to print.

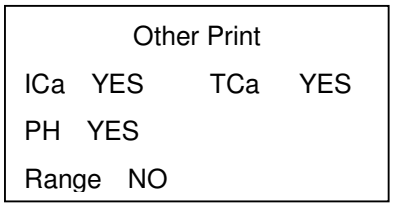

Figure 39

3.3.3.3 Parameter Setup

Choose Parameter in Setup menu then the display shows as Figure40.

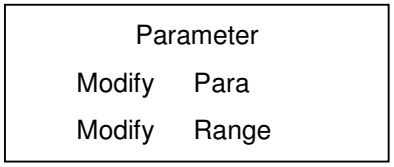

Figure 40

Choose “Modify Para”, the display shows as the Figure 41. The accuracy of high value(or middle value) and low value can be changed by adjusting the slope(k). The fixed error of high, normal and low values can be eliminated by adjusting intercept (d).

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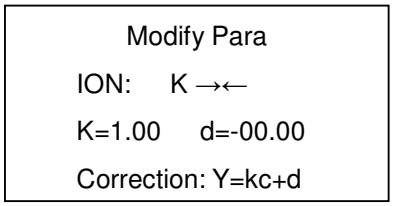

Figure 41

The slope (k) and intercept (d) are obtained according to the calculation of low value sample and normal value sample and respective target value. According to the four values (two target values: S1, S2 and two measured values: M1, M2), the value of k & d can be obtained through formula:

$$K = \frac{XS2-XS1}{XM2-XM1} \qquad d=XS1 - K*XM1$$

or $$K = \frac{XS3-XS1}{XM3-XM1}$$

To get the “K” and “d” value, operator must use the controls ranging from high, normal and low values, of the same manufacturer and the same lot, then calculate “K” and “d” values based the target values and measured values. The necessary data is shown as Table3.

Table 3 The necessary data for K and d values

Test	Low Value1		Normal Value2		High Value3	
	Target Value S1 (XS1)	Measure Value M1 (XM1)	Target Value S2 (XS2)	Measure Value M2 (XM2)	Target Value S3 (XS3)	Measure Value M3 (XM3)
K						
Na						
Cl						
Ca						

Test all the controls, calculate the “k” and ”d” value, then input “K, d” into the equipment. If good repetition is obtained, the measured values should be in accordance with the target ones.

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3.3.3.4 Range Setup

The normal range is the test results of healthy people. Choose Modify Range. The display shows as Figure42.

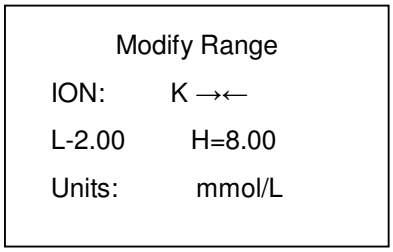

Figure 42

3.3.3.5 Calibration Setup

Choose “Calibrate”, the display shows as Figure 43. Under “Auto-Cal”., the device will calibrate automatically after measuring each sample, while under “Manual-Cal.” users must go back to the main menu to press “CAL” key and then the equipment will calibrate. If choose “Manual-Cal.”, we suggest to calibrate after each 5-10 measurements.

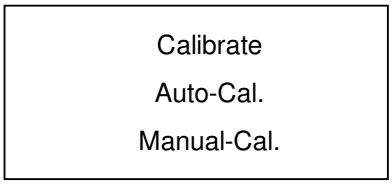

Figure 43

3.3.4 System Service

EA-analyzer has 4 system service programs as shown in Figure44.

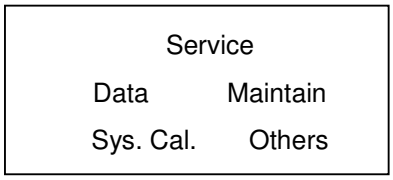

Figure 44

3.3.4.1 System Data

Choose ”Data” in the service menu, the display shows as Figure45.

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Figure 45

Choose “Data” to show the data of ID, while press “NO” to return to the main menu.

Choose “Slope” to show the electrode slope. The normal range is 30-80. Slope lower than 30 means the electrode is aged and needs to be replaced.

Choose “MV” to show MV. Value. The MV range of each electrode should be 50-120. If lower than 50MV, the electrode needs to be replaced.

If the electrode MV is lower than 50mv, the analyzer can’t pass calibration or the measurement is not correct.

Choose “Del. Data” to delete all the data.

3.3.4.2 System Calibration

Choose “Sys. Cal.” In the Service menu, the display shows as Figure46.

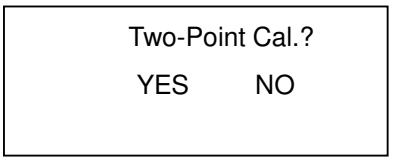

Figure 46

Choose “YES” the device will run two points calibration. It will test Std. A and Std. B to get the slope. Then test Std. A to check if the result is identical to the true value of Std.A. If yes, the calibration is passed, otherwise the display shows “continue calibrating?” Press “YES” to repeat the process of calibration.

Attention: If system calibration can not pass by 2 continuous times, press “NO” to enter the main menu and repeat the calibration after 30mins or ask for help from local service.

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3.3.4.3 Maintenance

Choose ”Maintain” in the Service menu, the display shows as Figure 47.

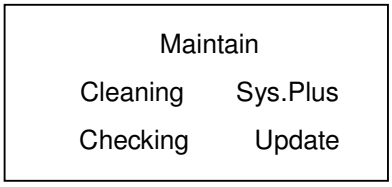

Figure 47

3.3.4.3.1 Cleaning

Choose “Cleaning”, the display shows as Figure 48.

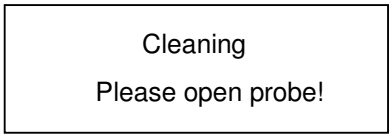

Figure 48

At this moment, open the probe to aspirate de-protein solution, then the display shows as Figure49.

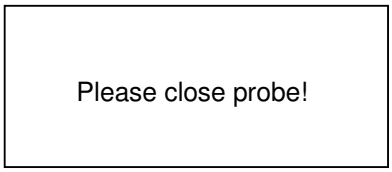

Figure 49

At this moment close the probe, the display shows as Figure50.

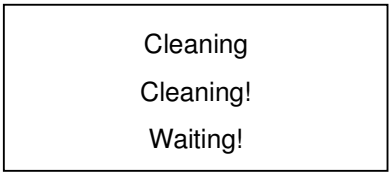

Figure 50

This is to remove protein from electrode and tube.

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3.3.4.3.2 Checking

Choose “Checking” in the Maintenance menu, the display shows as Figure 51.

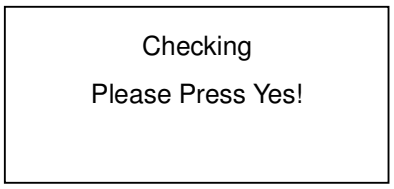

Figure 51

Press “YES”, the device will aspirate Std A automatically. Then the display shows as Figure 52.

Figure 52

After STD A is aspirated, the display shows as Figure 53.

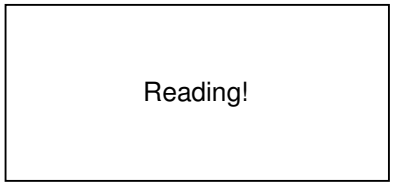

Figure 53

12 secs later, the display shows as Figure 54.

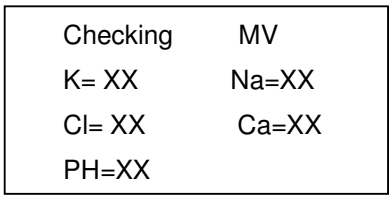

Figure 54

Note: The MV value will be refreshed in 1 second or so. If MV is not stable after 1 min. refreshing, it indicates MV is not stable, and the electrode needs to be maintained or changed.

Press “No” to return to previous page.

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3.3.4.3.3 Sys.Plus

System Plus is adjusted before the equipment leaves factory. There's no need for user to adjust it.

3.3.4.3.4 Update

Users do not need to update the system.

4. Maintenance

4.1 Daily Maintenance

-- Checking standard A or B is enough.

-- Checking the waste container is full or not.

-- The analyzer must be calibrated after changing reagent.

-- Prevent air into tube. If the air bubble exists inside the tube, it will cause error results. There are three ways to eliminate air bubbles:

a. Start-up again.

b. Repeat calibration so that the air bubble can be removed out of electrode.

c. Empty the waste container.

Note: The end of reagent tube must reach bottle's bottom.

4.2 Weekly Maintenance

Use detergent to remove protein and clean the tube. Removing protein must be done every week (For large quantity of test, please do it twice), because it plays an important role for extending the life of electrode. Operate it according to 3.5.3.1.

4.3 Half Year Maintenance

Change pump tubing.

Change electrode electrolyte.

Electrode electrolyte must be added if the internal solution is reduced otherwise stability of electrode will be decreased.

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How to add electrode electrolyte:

Rotate to open the head of electrode, empty the electrode solution and fill it full with electrolyte solution by syringe then cover the head. The electrode electrolyte does not need to be changed if the electrode works well.

Note:

a. The electrode sequence should not be reversed, otherwise air bubble will enter the electrode. Please remove air bubble before installing electrodes to the holder.

b. When adding electrolyte solution, the needle of syringe should not enter the electrode for avoiding damage the sensitive membrane.

If the pump tube is used for a long time, the protein will be deposited and cause wrong test result, so the analyzer must be cleaned regularly.

4.4 Shut down Maintenance

Before shutting down EA please maintain it as follows:

-- Take out reagent bottle and empty it.

-- Rinse to remove reagent inside tube according to set up steps.

-- Turn off electrical source.

-- Take out the electrode and store it.

-- Loose pump tube.

4.5 Precautions

-- EA-analyzer must keep 24 hours running for extending the life of electrode.

-- Performing QC must use electrolyte analyzer control (Ion).

-- No air-bubble in the sample during test or it must be measured again.

-- No air-bubble in the standard solution during calibration or it must be measured again.

Make sure all of the sample must be:

-- Measure sample as quick as possible. Measurement has to be conducted within 2 hours after it is collected.

-- Use heparin as anticoagulant.

-- Samples must be stored at room temperature, do not freeze.

-- Hemolysis can increase the K value.

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-- Don't use alkalescent heparin as anticoagulant including EDTA, citrate and Oxalate.

-- Don't use any unknown reagent to the instrument, because they may destroy the performance of ISE ion electrode.

5 Troubleshooting

5.1 Failure 1

No Electricity Input

Possible causes:

-- Power out.

-- Power wire is not correctly linked to electricity source.

-- Fuse breaks.

Solutions:

-- Shut down and wait for a moment and turn on again.

-- Make sure the power wire is well connected.

5.2 Failure 2

Deficiency of Repeatability

Possible causes:

-- Electrode is not stable.

-- Electrode is not activated.

-- Leakage between two electrodes.

-- Clot exists in electrode.

-- Contamination exists in the channel of electrode.

-- There is no KCl crystal in the reference electrode.

-- The MV of electrode is lower than 50mv.

-- The slope of electrode is lower than reference slope.

-- Strong interference of electromagnetism.

-- Not enough reagent or reagent has gone bad.

Solutions:

-- Calibrate again after 30 minutes.

-- Fix the electrode well.

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-- Take away the electrode & clean dust.

-- Clean with absolute alcohol.

-- Clean electrode.

-- Replace the reference electrode.

-- Calibrate again or replace electrode.

-- Remove the interference source & cover the shield correctly.

-- Replace reagent.

5.3 Failure 3

Low Accuracy

Possible causes:

-- "SYSTEM CALIBRATION" not done.

-- "SYSTEM CALIBRATION" can pass but the slope is beyond the limit.

-- The veracity of all items is not good.

-- The reagent goes bad.

-- k/d not set.

Solutions:

-- Do "SYSTEM CALIBRATION" 2 to 3 times.

-- Replace the corresponding electrode or reagent.

-- Replace the reference electrode.

-- Replace reagent.

-- Set k/d.

5.4 Failure 4

No Sample Sucked & Air Bubbles Inside Tube

Possible causes:

-- Sample probe or tube is blocked.

-- Tee connector is blocked.

-- Electrode is blocked.

-- Tube aged.

-- The tube is broken/ leaked.

Solutions:

-- Clean probe.

-- Clean channel.

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-- Clean electrode.

-- Replace tube.

-- Reinstallation of tube.

-- Replace pump tube.